

EXHIBIT H

Manual of PATENT EXAMINING PROCEDURE

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Additions to the text of the Manual are indicated by arrows (><) inserted in the text. Deletions are indicated by a single asterisk (*) where a single word was deleted and by two asterisks (**) where more than one word was deleted. The use of three or five asterisks in the body of the laws, rules, treaties, and administrative instructions indicates a portion of the law, rule, treaty, or administrative instruction which was not reproduced.

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701 Statutory Authority for Examination*35 U.S.C. 131. Examination of application.*

The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor.

The main conditions precedent to the grant of a patent to an applicant are set forth in 35 U.S.C. 101, 102 and 103.

35 U.S.C. 101. Inventions patentable.

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Form paragraph 7.04 copies 35 U.S.C. 101. See MPEP § 706.03(a).

35 U.S.C. 100. Definitions.

When used in this title unless the context otherwise indicates -

(a) The term "invention" means invention or discovery.

(b) The term "process" means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

(c) The terms "United States" and "this country" mean the United States of America, its territories and possessions.

(d) The word "patentee" includes not only the patentee to whom the patent was issued but also the successors in title to the patentee.

(e) The term "third-party requester" means a person requesting ex parte reexamination under section 302 or *inter partes* reexamination under section 311 who is not the patent owner.

702 Requisites of the Application [R-3]

When a new application is assigned in the Technology Center, the examiner should review the contents of the application to determine if the application meets the requirements of 35 U.S.C. 111(a). Any matters affecting the filing date or abandonment of the application, such as lack of an oath or declaration, filing fee, or claims should be checked **. For Image File Wrapper (IFW) processing, see IFW Manual sections 3.1 and 3.3.

The examiner should be careful to see that the application meets all the requisites set forth in MPEP Chapter 600 both as to formal matters and as to the completeness and clarity of the disclosure. If all of the requisites are not met, applicant may be called upon

EXAMINATION OF APPLICATIONS

716.02(g)

tive effectiveness over all compounds of the closest prior art. An applicant does not have to test all the compounds taught by each reference, “[h]owever, where an applicant tests less than all cited compounds, *the test must be sufficient to permit a conclusion respecting the relative effectiveness of applicant's claimed compounds and the compounds of the closest prior art.*” *Id.* (quoting *In re Payne*, 606 F.2d 303, 316, 203 USPQ 245, 256 (CCPA 1979)) (emphasis in original).).

>

III. < THE CLAIMED INVENTION MAY BE COMPARED WITH THE CLOSEST SUBJECT MATTER THAT EXISTS IN THE PRIOR ART

Although evidence of unexpected results must compare the claimed invention with the closest prior art, applicant is not required to compare the claimed invention with subject matter that does not exist in the prior art. *In re Geiger*, 815 F.2d 686, 689, 2 USPQ2d 1276, 1279 (Fed. Cir. 1987) (Newman, J., concurring) (Evidence rebutted *prima facie* case by comparing claimed invention with the most relevant prior art. Note that the majority held the Office failed to establish a *prima facie* case of obviousness.); *In re Chapman*, 357 F.2d 418, 148 USPQ 711 (CCPA 1966) (Requiring applicant to compare claimed invention with polymer suggested by the combination of references relied upon in the rejection of the claimed invention under 35 U.S.C. 103 “would be requiring comparison of the results of the invention with the results of the invention.” 357 F.2d at 422, 148 USPQ at 714.).

716.02(f) Advantages Disclosed or Inherent

The totality of the record must be considered when determining whether a claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made. Therefore, evidence and arguments directed to advantages not disclosed in the specification cannot be disregarded. *In re Chu*, 66 F.3d 292, 298-99, 36 USPQ2d 1089, 1094-95

(Fed. Cir. 1995) (Although the purported advantage of placement of a selective catalytic reduction catalyst in the bag retainer of an apparatus for controlling emissions was not disclosed in the specification, evidence and arguments rebutting the conclusion that such placement was a matter of “design choice” should have been considered as part of the totality of the record. “We have found no cases supporting the position that a patent applicant's evidence or arguments traversing a § 103 rejection must be contained within the specification. There is no logical support for such a proposition as well, given that obviousness is determined by the totality of the record including, in some instances most significantly, the evidence and arguments proffered during the give-and-take of *ex parte* patent prosecution.” 66 F.3d at 299, 36 USPQ2d at 1095.). See also *In re Zenitz*, 333 F.2d 924, 928, 142 USPQ 158, 161 (CCPA 1964) (evidence that claimed compound minimized side effects of hypotensive activity must be considered because this undisclosed property would inherently flow from disclosed use as tranquilizer); *Ex parte Sasajima*, 212 USPQ 103, 104 - 05 (Bd. App. 1981) (evidence relating to initially undisclosed relative toxicity of claimed pharmaceutical compound must be considered).

The specification need not disclose proportions or values as critical for applicants to present evidence showing the proportions or values to be critical. *In re Saunders*, 444 F.2d 599, 607, 170 USPQ 213, 220 (CCPA 1971).

716.02(g) Declaration or Affidavit Form

“The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001.” Permitting a publication to substitute for expert testimony would circumvent the guarantees built into the statute. *Ex parte Gray*, 10 USPQ2d 1922, 1928 (Bd. Pat. App. & Inter. 1989). Publications may, however, be evidence of the facts in issue and should be considered to the extent that they are probative.